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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,310	10/08/2003	Mattias Karlsson	58282 (47137)	7321

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EXAMINER	
PRICE, CRAIG JAMES	
ART UNIT	PAPER NUMBER
3753	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/682,310	KARLSSON ET AL.	
	Examiner	Art Unit	
	Craig Price	3753	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *08 January 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *28,29,35,37,38,40-51 and 53-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *28,29,35,37,38,40-51,53-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 28,29,35,37,38,40,41-50 and 52-58 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/8/2010 has been entered.

Claim Objections

2. Claim 28, line 10 and claim 29, line 12, "wherein the microfluicdevice" should be - - wherein the microfluidic device - - .

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28,29,35,37,38,40,41-50 and 52-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 28,29, 48, 49 and 57 recite the limitation "a substantially separate aqueous stream" is unclear as to if the streams are separate or not. Appropriate correction is required.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 28, 29, 38, 40, 48, 49, 51, 52, 53 and 56 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303).

Regarding claims 28, 29, 48 and 49, Benavides et al. disclose, as shown in Figure 21 a macroscale device (110,120 having a tubing outer diameter of 1/16 of an inch), which is interfaced with a microfluidic (100) device using double-sided tape (26, Col.8, Lns. 30-34) or transfer tape (Col.7, Lns. 61-65) to form a stable association between the microfluidic device and the macroscale device, wherein the double sided tape comprises a first adhesive surface which associates with the macroscale device and a second adhesive surface which associates with the microfluidic device, wherein the microfluidic device has a plurality of microchannels (Col.11, Lns. 58-63, Col. 12,

Lns. 6-11) suitable for containing a fluid stream, and wherein each microchannel comprises an outlet (Col. 11, Lns. 63-65) "for delivering a substantially separate aqueous stream into the sensor chamber", and at least one sensor (Col. 11, Lns. 58-63). The outlets of the microchannels intersect with at least one of the sensor chambers (the channels 22 intersect with "chambers" 114). Regarding "for delivery ...sensor chamber", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Benavides et al. disclose having a sensor but does not explicitly teach that the microfluidic device comprises a scanning mechanism for selectively exposing a sensor to multiple fluid streams from the plurality of microchannel outlets.

Orwar et al. disclose a cell-based biosensor which teaches the use of a scanning mechanism (8,17) for selectively exposing a sensor (9) to multiple fluid streams from the plurality of microchannel outlets, as shown in Figure 4A.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a scanning mechanism for selectively exposing a sensor to multiple fluid streams from the plurality of microchannel outlets as taught by Orwar et al. into the device of Benavides et al. in order to improve the resolution of the detected bioactive analytes (Col. 12 ,Lns. 37-42).

Regarding claim 37, Benavides et al. disclose that the one or more sensor chambers is for containing one or more cells (Col.11, Lns. 54-56).

Regarding claim 38, Benavides et al. disclose that the microfluidic device comprises at least one electrical element (58) "for performing planar patch clamp analysis". The limitation "for performing..." is considered as an intended use limitation. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Regarding claim 40, Benavides et al. disclose that the macroscale device comprises a pump head (120) connectable to a pressurized air supply (Col. 11, Lns. 53-54, "Fluids processed by the device can be "gaseous"...).

Regarding claim 51, Benavides et al. disclose a pressure chamber (20) between the macroscale device and the microfluidic device.

Regarding claim 52, Benavides et al. disclose that a system comprising a pump head device (110,120) which is interfaced with a microfluidic device (100) using double-sided tape (26) to form a stable association between the microfluidic device and the pump head device, wherein the double sided tape comprises a first adhesive surface which associates with the pump head device and a second adhesive surface which associates with the microfluidic device, and wherein a pressure chamber (20) is between the pump head device and the microfluidic device as shown in Figure 21, and

the microfluidic device comprises a plurality of microchannels (Col. 12, Lns. 7 – 11, "Sacrificial silicon dioxide is used to define microfluidic channels…").

Regarding claim 53, Benavides et al. disclose that the system comprises at least three microchannels as shown in Figure 23.

Regarding claim 56, Benavides et al. discloses that the system comprises three of more delivery channels (as shown in Figure 23) delivering one or more of a sample (Col. 11, Lns. 54-56), an agonist, or an agonist.

6. Claims 35 and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303) and further in view of Pfost (5,104,621).

Benavides et al. and Orwarr et al. have disclosed all of the features of the claimed invention although are silent to a system, wherein the microchannels correspond in number to the number of wells in a microtiter plate, and, wherein the microchannels connect to reservoirs in the microfluidic device and wherein the center-to-center distance of each reservoir corresponds to the center-to-center distance of the wells in the microtiter plate.

Pfost et al. disclose an analytical automated chemistry processing center which teaches the use of a microtiter plate (Col. 11, Lns. 45-48).

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize microtiter plates as taught by Pfost et al. into the combined system of Benavides et al. and Orwar et al. to have a system wherein the microchannels

correspond in number to the number of wells in an industry-standard microtiter plate, and, wherein the microchannels connect to reservoirs in the microfluidic device and wherein the center-to-center distance of each reservoir corresponds to the center-to-center distance of the wells in the microtiter plate, in order to have an automated material handling system which could transfer the samples from one well of one microtiter plate to a different well in another microtiter plate depending on the type of analysis desired (Col. 11, Lns. 45-53).

7. Claims 41-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303) and further in view of Bjornson et al. (6,103,199).

Benavides et al. and Orwar et al. have disclosed all of the features of the claimed invention although are silent to the system having the macroscale surface interfaced with a microfluidic surface of a device being a pump thereby being selected from the group consisting of a pump head, pump, degasser, flow meter, injector manifold, a pressure sensor, flow cell, concentration manifold or cartridges, a fitting or connector, a mixer, a compressor, an ultrasonic bed, an extractor, a focusing device, a dialysis chamber, an absorption chamber, a metabolite chamber, a toxicity chamber, a cell chamber, a detector, an RFID tag, a reagent vessel, a separation column, a focusing column, a size exclusion column, an ion-exchange columns, affinity columns, solid-phase extraction beds, a filter, a sieve, a frit, a depth filter, a heater, a heat exchanger, a cooler, a magnetic field generator, electric field generator, electroporation device, patch

clamp pipette, and one or more connections thereto, and that the detector is a fluorescence flow cell which is selected from the group consisting of a UV/Visible absorbance flow cell, a fluorescence flow cell, a conductivity flow cell, an electrochemical detector, a plasma detector, surface plasmon resonance detector and a mass spectrometry detector and that the detector is an optical sensor such, selected from the group consisting of a flow meter, a pressure transducer, a temperature sensor, a chemical sensor, an acoustic sensor, a color sensor, an optical sensor, a bar code sensor, a photothermal sensor, a photoacoustic sensor, and an RFID tag.

Bjornson et al. discloses a capillary electroflow apparatus which teaches the use of an optical detection device such as ultraviolet or fluorescence spectrometer (Col. 24, Lns. 1-4).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ an ultraviolet optical detection device as taught by Bjornson et al. into the combined assembly of Benavides et al. and Orwar et al. in order to "read the different types of substances being moved to different portions of the medium", so that "the information can be sent to the computer, which can adjust the speed of the waves or voltage distribution profiles being generated in order to more precisely fine tune the resolution of the substances being moved through the medium" (Col. 24, Lns. 6-12).

8. Claims 44,45,49 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303)

and further in view of Crandall et al. (6,352,766).

Benavides et al. and Orwar e al. have disclosed all of the features of the claimed invention although are silent to at least one adhesive side of the tape surface covered by a release liner prior to adhering the device surface of the macroscale or microfluidic device and adhesives on each side of the double sided tape comprise different types of adhesive and transfer tape forming a stable association between the microfluidic device and the macroscale device, wherein the transfer tape comprises a backing to which an adhesive surface is seperably attached and wherein a bond between the adhesive and the backing is weaker than a bond between the adhesive and the macroscale or microfluidic surface.

Crandall et al. disclose a low adhesion material which teaches a device as having at least one adhesive side of the tape surface is covered by a release liner (Col. 5, Lns. 38-41) prior to adhering the device surface of the macroscale or microfluidic device and adhesives on each side of the double sided tape comprise different types of adhesive (Col. 5, Lns. 41-45).

It would have been obvious to one of ordinary skill in the art at the time of invention to employ a system having at least one adhesive side of the tape surface is covered by a release liner prior to adhering the device surface of the macroscale or microfluidic device and adhesives on each side of the double sided tape comprise different types of adhesive and transfer tape forming a stable association between the microfluidic device and the macroscale device, wherein the transfer tape comprises a backing to which an adhesive surface is seperably attached and wherein a bond

between the adhesive and the backing is weaker than a bond between the adhesive and the macroscale or microfluidic surface as taught by Crandall et al. onto the combined device of Benavides et al. and Orwar et al. in order to permit the easy removal of the liner from the coated article (Col.1, Lns 21-30).

9. Claims 46 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303) and further in view of DiZio et al. (6,455,152).

Benavides et al. and Orwar et al. have disclosed all of the features of the claimed invention although are silent to the system having the adhesive on the tape is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive.

Dizio et al. disclose an adhesive coating article which teaches the use of the adhesive on the tape is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive (Col. 5, Lns. 39-41).

It would have been obvious to one of ordinary skill in the art at the time of invention to utilize an adhesive on the tape which is patterned onto a backing and, wherein at least one surface of the tape comprises portions that are coated with adhesive and portions that are not coated with adhesive as taught by Dizio et al. onto the combined system of Benavides et al. and Orwar et al. in order to reduce the surface contact between the transfer surface and the adhesive (Col. 5, Lns. 9-20) to have a

better transfer of adhesive during the manufacturing process when joining the microfluidic and macroscale devices.

10. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303) and further in view of Chiu et al. (7,470,518, available through the provisional application 60/356,377).

Benavides et al. and Orwar et al. disclose all of the features of the claimed invention although are silent to a system having the sensor be a cell based biosensor and in which the cell based biosensor is a receptor.

Chiu et al. disclose a microfluidic device which teaches the use of a biosensor that is a receptor, as disclosed in the originally filed specification in the provisional application on page 30, the GPCR sensor is a cell based biosensor which is a receptor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cell based biosensor which is a receptor as taught by Chiu et al. into the combined system of Benavides et al. and Orwar et al. in order to measure the desired characteristic of the sample.

11. Claims 54 and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benavides et al. (6,443,179) in view of Orwar et al. (6,455303) and further in view of Stanto et al. (7,125,660, available through the application 09/952,680).

Benavides et al. and Orwar et al. disclose all of the features of the claimed invention although are silent to a system having the sensor be a cell based biosensor and in which the cell based biosensor is a receptor.

Stanton et al. disclose a microfluidic device which teaches the use of a biosensor that is a receptor, as disclosed in the originally filed specification in the provisional application on page 57, lines 6-13, the GPCR sensor is a cell based biosensor which is a receptor.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ a cell based biosensor which is a receptor as taught by Stanton et al. into the combined system of Benavides et al. and Orwar et al. in order to measure the desired characteristic of the sample.

Double Patenting

12. Applicant is advised that should claims 28 and 29 be found allowable, claims 48 and 49 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claims 28,29,48,49 and 57 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of U.S. Patent No. 7,563,614 to Orwar et al. in view of Benavides et al. (6,443,179). Orwar et al. '614 disclose a substrate for changing a solution environment around a sensor, the substrate comprising a plurality of microchannels, each microchannel comprising an outlet, and at least one sensor chamber, wherein the outlets of the microchannels intersect with at

least one of the sensor chambers, a scanning mechanism for selectively exposing a sensor to multiple fluid streams from the plurality of microchannel outlets, although are silent to having a macroscale device which is interfaced with a microfluidic device using double-sided tape or transfer tape to form a stable association between the microfluidic device and the macroscale device, wherein the double sided tape comprises a first adhesive surface which associates with the macroscale device and a second adhesive surface which associates with the microfluidic device, wherein the microfluidic device has a plurality of microchannels suitable for containing a fluid stream, and wherein each microchannel comprises an outlet "for delivering a substantially separate aqueous stream into the sensor chamber", and at least one sensor.

Benavides et al. disclose, as shown in Figure 21 a macroscale device (110,120 having a tubing outer diameter of 1/16 of an inch), which is interfaced with a microfluidic (100) device using double-sided tape (26, Col.8, Lns. 30-34) or transfer tape (Col.7, Lns. 61-65) to form a stable association between the microfluidic device and the macroscale device, wherein the double sided tape comprises a first adhesive surface which associates with the macroscale device and a second adhesive surface which associates with the microfluidic device, wherein the microfluidic device has a plurality of microchannels (Col.11, Lns. 58-63, Col. 12, Lns. 6-11) suitable for containing a fluid stream, and wherein each microchannel comprises an outlet (Col. 11, Lns. 63-65) "for delivering a substantially separate aqueous stream into the sensor chamber", and at least one sensor (Col. 11, Lns. 58-63).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a macroscale device which is interfaced with a microfluidic device using double-sided tape or transfer tape to form a stable association between the microfluidic device and the macroscale device, wherein the double sided tape comprises a first adhesive surface which associates with the macroscale device and a second adhesive surface which associates with the microfluidic device, wherein the microfluidic device has a plurality of microchannels suitable for containing a fluid stream, and wherein each microchannel comprises an outlet as taught by Benavides et al. with the substrate of Orwar et al. in order to provide for a "standardized electro-microfluidic package that can be plugged into a fluidic printed wiring board (Benavides et al, Col. 4, Lns. 36-38).

Response to Arguments

13. Applicant's arguments with respect to claims 28, 29, 35, 37, 38, 40-51, 53-58 have been considered but are moot in view of the new ground(s) of rejection.

Applicant's argument regarding the 112 rejection where the limitation "a substantially separate aqueous stream" is unclear, is not persuasive, in that the limitation in the broadest reasonable interpretation covers portions of a stream which are not separate, due to the use of the term substantially. The given meaning of the limitation "a substantially separate aqueous stream" described in the specification, does not cover streams which are "not separate" and therefore the limitation is unclear.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Craig Price whose telephone number is (571) 272-2712. The examiner can normally be reached on 8AM - 4:30PM M-Fri, Increased flex time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robin Evans can be reached on (571) 272-4777. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CP/ 27 February 2010 /John Rivell/
Primary Examiner, Art Unit 3753

/C. P./
Examiner, Art Unit 3753